



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent Commercialization License: CD28H Domain-Containing Chimeric Antigen Receptors and Methods of Use

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: .The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Ankarys Therapeutics Inc., located at 110 Cumberland Street, Suite 520, M5R 3V5, Toronto, Ontario, Canada, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Dawn Taylor-Mulneix, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health; phone number 301-767-5189, or dawn.taylor-mulneix@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement: PCT Patent Application Number PCT/US2020/024985, filed

March 26, 2020, entitled “CD28H Domain-Containing Chimeric Antigen Receptors and Methods of Use” (HHS Reference No. E-097-2020-00-PCT), and U.S. and foreign patent applications claiming priority to the aforementioned application.

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide, and the field of use may be limited to: “Use of natural killer cell immunotherapies for the treatment of multiple myeloma, non-Hodgkin lymphoma, and pancreatic cancer”.

Engineered chimeric antigen receptors (CARs) that are expressed in cytotoxic T cells and natural killer (NK) cells have been used to specifically target tumor cells. However, CAR-T and CAR-NK cells are still subject to down regulation by their inhibitory receptors after injection into patients.

Scientists at NIAID have developed CAR constructs that overcome inhibition of NK cells by receptors for human major histocompatibility complex molecules HLA-E and HLA-C, based on in vitro studies. The CAR contains an antigen binding domain of receptor CD28 homolog (CD28H), a CD28H transmembrane domain (TM), a CD28H signaling domain, and other intracellular signaling domains, such as 2B4 (CD244) and CD3 zeta chain (CD3zeta). A variant of this CAR, in which the antigen binding domain of CD28H is replaced by a single-chain antibody variable region (scFv) that binds to CD19, rendered NK cells resistant to inhibition by HLA-E and HLA-C on CD19+ tumor cells. An abstract for this invention was published in the Federal Register on April 22, 2020.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent commercialization license will be royalty bearing, and may be granted unless within fifteen (15) days from the date of this published notice, the

National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: October 19, 2021.

Surekha Vathyam,
Deputy Director,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases.

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